No. 97-1345 (2)

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

October Term, 1997

DAXOR CORPORATION, et al.,

Petitioners,

- v. -

STATE OF NEW YORK DEPARTMENT OF HEALTH, et al.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE COURT OF APPEALS OF THE STATE OF NEW YORK

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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Question Presented

Whether certiorari should be granted to examine petitioners' Due Process claim of entitlement to State licenses to operate various medical facilities, where (1) petitioners operated those facilities prior to 1994 pursuant to either provisional State licenses or limited licenses annually issued by the City of New York; (2) the New York State Legislature withdrew New York City's authority to issue licenses in 1994, and mandated that no such facility operate in New York State unless licensed by the New York State Department of Health (DOH); and (3) DOH regulations provided petitioners with no assurance that their license applications would be granted.

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Brief in Opposition to Petition For Writ of Certiorari

Opinions Below

Respondents adopt the statement of opinions below set forth in the petition for a writ of certiorari. (Pet. 2).[1]

Jurisdiction

Respondents adopt the statement of jurisdiction set forth in the petition for a writ of certiorari. (Pet. 2).

Statement

A. New York State Regulation of Clinical Laboratories, Blood Banks and Tissue Facilities

Recognizing the substantial public interests and health concerns affected by the operation of blood banks, clinical laboratories, semen banks and insemination sites in New York State, the New York Legislature has provided for the regulation of these entities by the State Department of Health ("DOH"). *See*, New York Public Health Law ("PHL") §§ 570 *et seq.* (McKinney Supp. 1997)(regulation of blood banks and clinical laboratories); PHL §§ 4360 *et seq.* (McKinney Supp. 1997)(regulation of tissue banks, including semen banks and insemination sites). As part of the regulatory process, the Legislature has directed DOH to issue operating permits to such medical sites (PHL § 574; PHL § 4364[1]), and has prohibited issuance of permits to any facility unless DOH determines that the facility will be operated in the manner required by the State's public health laws and regulations. PHL §575(2) (clinical laboratories and blood banks); PHL § 4364(3) (tissue banks). DOH has issued regulations implementing this statutory

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[1] Numbers in parentheses preceded by "Pet." refer to pages in the petition for a writ of certiorari in No. 97-1345.

mandate. *See, e.g.*, N.Y. Comp. Codes R. & Regs. tit. 10 (hereafter "10 NYCRR") § 52-2.5 (5) (1995) (licenses to operate a tissue bank will be denied where the director of the medical site does not have the "character and competence to ensure that [the facility] is ... operated in accordance with the law.").

Under the Public Health Law, each specific site at which a laboratory tests materials or performs tissue banking must obtain a separate operating permit, which must specify the laboratory procedures or type of tissue banking authorized. PHL §§ 574; 575(1)(5)(6); 4364(2). The Legislature has limited the term of laboratory and blood banking permits to one year. PHL § 575(4).

B. The City of New York's Blood Bank and Clinical Laboratory Licensing Authority and Its Repeal

Between 1964 and 1994, blood banks and clinical laboratories operating exclusively within New York City were licensed by the City; laboratories operating outside New York City were licensed by the State. *See* PHL § 574(2) (repealed 1993). In 1993, the Legislature amended this regulatory system, abolishing the City licensing system and requiring all facilities to obtain more general State licenses or to cease operation. *See* 1993 N.Y. Laws, Chapter 436. Chapter 436 was signed into law on July 26, 1993, and became effective on July 1, 1994.

As noted by the New York State Court of Appeals in its decision below, the purpose of this statutory amendment was not merely "to ease the regulatory burden on license applicants and avoid duplicative and inconsistent regulations[.]" (Pet. App. 5a).[2] Rather, "the amendment served other purposes as

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[2] "Pet. App." denotes the appendix to the petition for a writ of certiorari in No. 97-1345.

well, among them more closely monitoring the qualifications of such facilities and making the requirements for certification more stringent, to comply with federal law[.]" (Pet. App. 5a-6a).

To aid the transition, DOH informed all blood banks and clinical laboratories operating under City licenses -- including petitioners -- that, upon their application for a State license, they could continue to operate in New York City, but not in the State at large, "until final issuance or denial of your State credentials, i.e., your certificate of qualification or your laboratory permit." (R. 585)[3] (emphasis added).

C. New York State Regulation of Semen Banks and Insemination Sites

Prior to 1989, neither New York City nor New York State regulated the operation of semen banks and artificial insemination sites. 10 NYCRR Subpart 58-7 (1989), which was succeeded by 10 NYCRR Subpart 52-2 (1991). Following the institution of a State permit requirement in 1991, operators of these facilities both within and outside New York City were eligible to apply to DOH for provisional licenses while their applications were evaluated. 10 NYCRR § 52-2.2(e). Under DOH regulations, such provisional licenses are issued on a temporary basis, expire upon determination of the underlying application, and may be revoked at any time, without a hearing, if DOH "finds that the [site] is not operated in substantial compliance with the applicable [DOH regulations]." *Id.*.

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[3] "R" denotes the record on review in the New York State Court of Appeals.

D. Petitioners' Licensing History

Petitioner Daxor Corporation owns and operates a blood bank, semen bank and clinical laboratories in New York City through its divisions, petitioners Scientific Medical Systems/Parkmed ("SMS") and Idant Laboratories. Prior to July 1, 1994, petitioners operated their blood bank and clinical laboratories pursuant to City of New York permits. The last of those permits were issued on January 26, 1994 and expired, by their express terms, on June 30, 1994, the date that the City licensing system ceased to exist. Petitioners at no time held a City permit of a term exceeding one year, and all permits were subject to annual reapplication.

During the time petitioners were licensed to operate by the City, they periodically applied to DOH for State operating licenses. However, those applications were consistently denied by DOH on the same grounds which led DOH to deny the applications in the instant matter, i.e., a determination that petitioners lacked the character and competence to ensure that their facilities would be operated in conformance with the law. (R. 715-19). At least two of those determinations were also challenged in the New York State Courts. (R. 715-19).

Between 1991 and 1995, petitioners operated their semen bank and insemination site pursuant to provisional licenses issued by DOH under 10 NYCRR § 52-2.2.

E. DOH's Denial of Petitioners' License Applications and the Administrative Proceedings Below

Petitioners submitted a series of permit applications to DOH for the operation of their semen bank, insemination site, blood bank, and clinical laboratories between 1991 and mid-1994. DOH denied all four of petitioners' applications for State operating licenses. As set forth in a letter sent to petitioners on

September 30, 1994 (the "Denial Letter"), DOH based its denial upon the determination that petitioners "do not have the character and competence to ensure that the [medical sites] are operated in accordance with the law, and will be so operated." (R. 111, Denial Letter at p. 2). In making this determination, DOH reviewed its extensive prior experience with Daxor Corporation and its operator, Dr. Feldschuh, and noted that:

> Despite numerous letters advising of specific violations, deficiency statements describing numerous substantiated violations of statutes and regulations, administrative hearings, New York City Department of Health tribunal actions, proposed and final denials of clinical laboratory and blood bank permit applications, and serious administrative charges against the semen bank, [petitioners] continue to operate in a manner which is in violation of existing statutes, regulations and standards.

(*Id.*). Violations cited by DOH in its letter included:

(i) On July 28, 1986 Dr. Feldschuh and SMS were found guilty by New York City's administrative tribunal of performing laboratory tests at another New York City clinic, known as "VIP", without a requisite laboratory permit. Dr. Feldschuh personally appeared at the hearing and admitted to at least 23 violations of this type. (R. 114-20, Denial Letter, Appendix 1).

(ii) On January 22, 1991, Dr. Feldshuh again pled guilty, this time in a New York State Department of Health proceeding, to operating an unlicensed laboratory. (R. 121-26, Denial Letter, Appendix 2). Specifically, Dr. Feldschuh admitted that Idant and SMS had operated unlicensed laboratories at two different sites in Buffalo during 1990, where Idant had actually stationed unsupervised employees to perform and report laboratory tests,

despite the fact that Idant had only a New York City laboratory permit.

(iii) A DOH investigation, performed in 1994 with respect to the pending license applications, found that, even after stipulating in 1986 that it would cease unauthorized and unlicensed testing at the VIP clinic, Idant continued to perform unlicensed testing at VIP and had altered its records to conceal this activity. (Denial Letter, R. 132-77, Appendix 5-8).[4]

(iv) Idant's clinical laboratory director from 1988 to 1994, Dr. Matthew Klein, gave DOH a sworn statement that, while employed at Idant, he regularly examined Idant specimens, at his home in New Jersey, rather than on site at Idant as required by regulation. This misconduct was corroborated by statements and records from the courier service which ferried the specimens between Idant and Dr. Klein's home. (R. 178-89,

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[4] Addressing this violation, petitioner Feldschuh noted in an affidavit in the instant case (R. 762):

> Petitioners became aware of a potential violation during its self-audit in the fall of 1993 and winter of 1994 ... At that time I instructed all Idant personnel that testing was to be performed at Idant, not at VIP. When in March 1994 I became aware that Mr. Bulatao was performing testing at VIP, I contacted ... the director of VIP [and] ... she agreed that to the extent VIP desired Mr. Bulatao to perform functions on its premises ... VIP would pay Mr. Bulatao, as one of its employees for these services.

Petitioner Feldschuh thus conceded that eight years after stipulating to cease and desist from operating an unlicensed laboratory at VIP, he "discovered" that the illegal operation continued and that his response to this violation was simply to enter into an agreement with VIP enabling VIP itself to operate an unlicensed laboratory through the services of one of his employees.

Denial Letter, Appendix 9 & 10). Idant's records falsely stated that the tests were being performed on site at Idant. (*Id.*).

(v) Despite being informed by New York City's Department of Health on June 11, 1992 that its authorization to perform urine pregnancy testing was deleted from its New York City laboratory permit, Idant illegally continued to perform this test until July 1994. (R. 190-206, Denial Letter, Appendix 11).

F. The Proceedings in the State Courts

Petitioners commenced a proceeding in the Supreme Court, New York County, to review DOH's denial of its license applications. In that proceeding, petitioners alleged, *inter alia*, that they had been denied due process of law and that they were the victims of an elaborate regulatory conspiracy. (Pet. App. 12a). By an unpublished decision and order dated July 17, 1995, the New York Supreme Court denied the petition. (Pet. App. 18a-21a).

On appeal, the Appellate Division, First Department, reversed. (Pet. App. 14a-17a). Interpreting chapter 436, and without a detailed discussion of petitioners' claims of entitlement to a property interest under state or federal law, the Appellate Division concluded that the statute did not grant DOH the authority to review the applications of the former New York City licensed banks:

> Nothing in the legislation [repealing the City licensing system] suggests that any such abolition of existing operating licenses was intended .... That the State Legislature may abolish a license without providing a licensee with a hearing, as [DOH] asserts, is of little significance. We conclude that the Legislature has not done so in this instance, but has merely provided that the State Department of Health

> assume responsibility for the regulation of existing facilities[.]

(Pet. App. 16a-17a) (emphasis in original).

On appeal, the New York State Court of Appeals reversed the order of the Appellate Division, in an opinion by Chief Judge Kaye. (Pet. App. 1a-13a). Reviewing the legislative history of the 1993 amendment to Public Health Law § 574 eliminating the City licensing system, the Court of Appeals rejected the Appellate Division's holding that the Legislature had intended to "grandfather" City-licensed facilities into the State system. (Pet. App. 5a-6a). Noting the intent of the legislation to make "the requirements for certification more stringent," (Pet. App. 6a), the court found that the Appellate Division's reading of the amendment would contravene the mandate, under PHL § 575(2), that DOH refuse to license any blood bank or clinical laboratory "unless [it] finds that the clinical laboratory or blood bank is competently staffed and properly equipped, and will be operated in the manner required by this title." (Pet. App. 6a-7a). Because it would result in the granting of fully licensed status to petitioners' facilities without any review by DOH, the court held that the lower court's ruling was contrary to the general intent of the statute. (*Id.*).

The Court of Appeals carefully considered and rejected petitioners' argument that a property interest had arisen by virtue of their "years of continuous operation under the City's licensing scheme and provisional State licenses." (Pet. App. 9a-11a). Applying this Court's analytical framework set forth in *Board of Regents v. Roth*, 408 U.S. 564 (1971), the court examined both the amount of discretion that DOH enjoyed in passing upon the applications, and the nature of the discretionary criteria to be applied in such reviews, and concluded that no property right had arisen. (Pet. App. 9a-11a).

Finally, the court concluded that, in light of petitioners' past conduct, the determination to deny the applications was rational. (Pet. App. 3a-4a, 11a-13a). It rejected the claim that the denial of licenses reflected an "elaborate regulatory conspiracy" against petitioners as unsupported by the record. (*Id.*).

Petitioners subsequently filed a petition for a writ of certiorari.

ARGUMENT

IN THE ABSENCE OF ANY CONFLICT OR INCONSISTENCY BETWEEN THE DECISION OF THE COURT OF APPEALS AND THE DECISIONS OF THE FEDERAL COURTS, NO REASON EXISTS FOR THE GRANT OF CERTIORARI.

The petition for certiorari should be denied because the New York State Court of Appeals, in reaching its decision in the instant matter, correctly applied this Court's well-settled analytical principles addressing the creation of property interests under the Fourteenth Amendment. Foremost among such principles -- and virtually unmentioned in the petition -- are those set forth in this Court's ruling in *Board of Regents v. Roth*, 408 U.S. 564 (1971) (a legitimate claim of entitlement to a benefit provided by government must be rooted in existing rules or understandings "that stem from an independent source such as state law").

As we have noted above, New York State recognized two species of blood bank license prior to 1994. State licenses, authorizing operations everywhere in New York State except New York City, could issue only upon a finding by DOH that the applicant was likely to conform its operations to law. PHL

§ 575(2). The more limited City license, issued by the City Department of Health and authorizing operations only within New York City, required no such finding by DOH. During the time petitioners enjoyed their City licenses, their applications for State licenses were consistently denied on grounds of insufficient character. In 1994, New York's Legislature then abolished the entire City licensing system and imposed the DOH character and competence requirement upon petitioners and all other former holders of City licenses.

Under these facts, the Court of Appeals correctly held that petitioners had no "legitimate claim of entitlement" to State licenses under *Roth* (408 U.S. at 577-578). In light of the significant discretion granted to DOH under the statute to review applications, a DOH determination that an applicant could not be trusted to observe strictly State laws and regulations does not implicate a "property" interest or entitle the applicant to an adversarial hearing. Such a conclusion is in full accord with *Roth*, which held that the expectations of an applicant for State benefits must be legitimate and not merely a unilateral expectation. Nothing in the City licensing system, or in the legislation which abolished it, or in the State of New York's statutes or regulations, gave petitioners any guarantee or even strong expectation that DOH would automatically license them to operate, or approve their character, either before or after the repeal of the City licensing system. Petitioners' receipt of City licenses gave them no expectation of State licenses under a different statewide regulatory program. Indeed, since DOH had consistently denied all of their prior applications for State licenses, they had no basis for a belief that they would be granted licenses under the new system.

Not only have petitioners failed to demonstrate entitlement to State licenses -- they have failed even to show an entitlement to annual renewal of their City licenses prior to 1994. They made no record of the basis for such an entitlement before the courts

below, claiming only that their long operating history and the importance of the license to their operations established a property interest. (*See* Pet. App. 7a, n. 2). This is plainly insufficient under *Roth*.[5]

Petitioner's contrary contentions are meritless. Indeed, unable to address the principles of *Roth*, petitioners instead rely upon a series of cases which deal either with the revocation of licenses during their term, or which involve governmental benefits which are non-discretionary and to which an "entitlement" can therefore be said to exist. *See, e.g., Barry v. Barchi*, 443 U.S. 55 (1979) (summary suspension of an existing horse trainer's license during its term); *Bell v. Burson*, 402 U.S. 535 (1971) (suspension of an existing automobile driver license during its term); *Memphis Light, Gas & Water Div. v. Craft*, 436 U.S. 1 (1978) (non-discretionary grant to all Memphis utility customers of an absolute entitlement to receive electrical service); *Herz v. Degnan*, 648 F.2d 201 (3d Cir. 1981) (reapplication process a mere formality and approval of applications "automatic"). These cases, and the legal principles which they reflect, are simply irrelevant to the matter at bar. As the Court of Appeals correctly noted (Pet. App. 7a), "[w]hile existing licenses cannot be revoked without a hearing, there is no similar right for initial applications or renewals of licenses [citations omitted]." Moreover, as we have noted above, the statutory framework for issuance and renewal of licenses

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[5]We note in passing that the Legislature's abolition of the City's licensing authority did not violate petitioners' right to due process. *See, e.g., Atkins v Parker*, 472 U.S. 115, 129-130 (1985) (an existing, legislatively based property entitlement does not limit the legislature's power to substitute a different, less valuable entitlement at a later date). If petitioners had any conceivable entitlement to renewal of their limited City permit -- which they did not -- New York's Legislature was free to abolish that entire species of permit without violating their constitutional rights.

afforded ample discretion to the licensing authority, and provided no basis for a belief that the application process was a mere formality.

In sum, the decision of the New York State Court of Appeals is fully consistent with the decisions of this Court, the federal Courts, and well-settled principles of due process. The petition should be denied.

CONCLUSION

The Petition For A Writ Of Certiorari Should Be Denied.

Dated: New York, New York
March 18, 1998

Respectfully submitted,

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